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10/751,292	01/02/2004	Mark A. Hoffman	CRNC.107055	1596

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,292	HOFFMAN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 32-52 are pending.

Claims 1-31 are cancelled.

Claims 32-52 have been examined.

Claims 32-52 are rejected.

Priority

This application, filed on 02 January 2004, is a continuation in part of application No. 09/981248 which was filed on 16 October 2001 and claims priority to Provisional application No. 60/509023, filed on 06 October 2003.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a new ground of rejection.

Claims 32-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 32-40 and 49-52 are directed to a process of predicting the likelihood that a person has a mutated form of a gene. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, “Determine Whether the Claimed Invention Complies with 35 USC101”. The claims are directed to processes. Here the claims are

directed to the abstract idea of predicting the presences of mutated gene. The processes do not recite a physical transformation of matter from one state to another. Giving the claims the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey* (*In re Comiskey*, 84 USPQ2d 1670) the court established that "the application of human intelligence to the solution of practical problems is not and of itself patentable" (at 1680). In *Comiskey*, the court stated explicitly "mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application" (at 1679). The court in *Comiskey* stated, "Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed" (at 1680). The court's recent decision in *In re Bilski* confirmed, "a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing" (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. Claims 32-40 and 49-52 recite providing an output or a response to a user. The output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in *Comiskey*, stated "the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that '[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula'" citing *Flook* (437 U.S. at 586, 590). The recent decision in *Bilski* confirmed the court's position regarding insignificant

pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 13-96-1397).Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No. 2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Claims 41-48 are directed to a system comprising modules. The specification teaches at p. 5, paragraph [0020] that modules are programs. The MPEP, at 2106.01, guides that computer programs *per se* are non-statutory. The claims are directed a program *per se* and are non-statutory.

Claims 36 and 50 are directed to an embodiment in which the method's instructions are embodied on a computer readable media. At p. 6, paragraph [0022], the specification teaches "computer readable media may comprise computer storage media and communication media". [0022] further describes communication media as a carrier wave. As such an embodiment of the claims read on non-statutory subject matter (In re Nuijten 84 USPQ2d 1495 (2007)).

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 42-45 and 48 as indefinite under 35 USC 112, second paragraph is withdrawn in view of the amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 41, and 49 recite the limitation to "apply genetics to the at least one of clinical agent or the clinical event". The metes and bounds of the claims are rendered indefinite by the phrase. It is unclear how genetics is applied to a clinical agent which is not genetic in nature. If applicant intends to use genetic techniques to characterize a person's response to one of a clinical agent or clinical event, then it would be beneficial to use such language. Claims 33-40, 42-48, and 50-52 are also rejected because they depend from claims 32, 41, and 49, and thus contain the above issues due to said dependence.

Claim Rejections - 35 USC § 103

Response to Arguments

The rejection of claims 32-52 as unpatentable over Pathak et al., in view Yan et al. (Drug Information Journal, Vol. 34, pp. 1247-1260, 2000), Roses (Nature, Vol. 405, p. 857-865, 15 June 2000), and Wolf et al. (British Medical Bulletin, Vol. 55, No. 2, p. 366-386, 1999) and in view of Kobrinskii et al. under 35 USC 103(a) is withdrawn in view of the amendments to the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claim 32-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al (WO 2001/01218), in view of Pathak et al.

The claims are directed to a method (claims 32-40 and 49-52) and system (claims 41-48) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a

database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

Akers et al shows a method and system in which an electronic order for a clinical agent is received (col. 4, line 37-40). Akers shows that the order is automatically checked for adverse reactions (col. 4, line 49-55). Akers shows that a table is searched to identify conflicts with the requested drug. Akers shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

Akers does not show that the conflicts correlate genetic findings associated with the clinical agent or drug.

Denton et al shows that mutations in genes effects how an individual responds to a clinical agent (p. 3). Denton shows the mutations in a gene can produce atypical events. Denton et al shows the determination of whether a mutation results in an atypical event (p. 48) Denton et al shows the correlation mutations in genes with a person's response to a particular drug in a database, which reads on a table (p. 70). Denton et al shows the database includes genetic information of the patient and family members (p. 72). Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed

immediately rather than relying on a trial and error approach to find the optimal drug (p. 6).

Akers et al in view of Denton et al. do not show the generation of likelihood that person has a mutation

Pathak et al shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2, para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Regarding claims 34 and 43, Pathak et al. teach knowledge source 2 concerned with allele inheritance relations with in the pedigree (p. 165, col. 2, "allele flow"). Regarding claims 35 and 44, Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-

analysis"). Regarding claim 36, Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Regarding claim 39 and 48, Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Regarding claims 33, 40, 42 and 45, Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al because Pathak et al shows the system provides the advantage of streamlining the computation of genetic risk.

Double Patenting

Response to Arguments

The provisional rejection of claims 32-39, 41-47, and 49-52 under the grounds of nonstatutory obviousness-type double patenting is withdrawn in view of the terminal disclaimer filed on 17 February 2009.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

16 July 2009